



Electronic Request for Proposal

SECTION A – SOLICITATION/CONTRACT FORM

OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE CMB WEBSITE <http://www.niaid.nih.gov/contract/default.htm> FOR ANY POSSIBLE SOLICITATION AMENDMENTS THAT MAY BE ISSUED. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE.

Purchase Authority: Public Law 92-218, as amended. NOTE: The issuance of this solicitation does not commit the government to an award.			
RFP Number: NIH-NIAID-DMID-02-24	Just In Time: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Small Bus. Set-Aside <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No 8(a) Set-Aside <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No NAICS Code: 54171 Size Standard: 500 or Fewer Employees	Level of Effort: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
TITLE: U.S. Based Collaboration In Emerging Viral and Prion Diseases			
Issue Date: Wednesday, November 21, 2001	Due Date: Friday, February 15, 2002 Time: 4:00 PM, Local Time	Technical Proposal Page Limits: <input type="checkbox"/> Yes (see "How to Prepare and Submit Electronic Proposals") <input type="checkbox"/> No	
ISSUED BY: Paul D. McFarlane Senior Contracting Officer 6700-B Rockledge Drive MSC 7612, Room 2230 Bethesda, MD 20892-7612		<input checked="" type="checkbox"/> <i>We reserve the right to make awards without discussion.</i>	
		NO. OF AWARDS: <input type="checkbox"/> Only 1 Award <input checked="" type="checkbox"/> Multiple Awards	PERIOD OF PERFORMANCE: 7 years beginning on or about 09/27/2002
Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See SECTION J - Attachments)			
The Official Point of Receipt for the purpose of determining timely delivery is the Contract Management Branch as stated above. The paper copy with original signatures is the official copy for recording timely receipt. If the paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered LATE and handled in accordance with HHSAR 352.215-70 entitled "Late Proposals and Revisions" located in this Solicitation. FACSIMILE SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.			
POINT OF CONTACT -- Paul D. McFarlane --COLLECT CALLS WILL NOT BE ACCEPTED--			
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TABLE OF CONTENTS

SECTION A -- SOLICITATION/CONTRACT FORM COVER PAGE

INTRODUCTION AND BACKGROUND

STATEMENT OF WORK

NOTES TO OFFERORS

REPORTING REQUIREMENTS and OTHER DELIVERABLES

SECTIONS B – H -- UNIFORM CONTRACT FORMAT - GENERAL

SECTION I -- GENERAL CLAUSES and ADDITIONAL CLAUSES / SUBSTITUTED CLAUSES

SECTION J -- LIST OF ATTACHMENTS

**SECTION K -- REPRESENTATIONS AND CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS OR
QUOTERS (NEGOTIATED)**

SECTION L -- INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

1. General Information
2. Instructions to Offerors
 - a. General Instructions
 - b. Technical Proposal Instructions
 - c. Business Proposal Instructions

SECTION M -- EVALUATION FACTORS FOR AWARD

U.S. Based Collaboration In Emerging Viral and Prion Diseases
NIH-NIAID-DMID-02-24

INTRODUCTION

The use of interactive research units focused on a specific need has proven to be a successful model that serves as both a responsive infrastructure capable of rapidly implementing new activities and a mechanism to provide cross-fertilization of ideas. The Request for Proposals (RFP) is being designed around this model to support interactive research on emerging viral diseases.

NIAID intends to establish several multi-disciplinary research units/contracts to develop and evaluate the scientific information and tools needed by the Government to control emerging viral and viral-like diseases. The units will conduct collaborative, interactive, interdisciplinary research. The units must be capable of quick response to threats posed by emerging diseases. One or more units will provide the capability to address scientific questions arising from the emergence of flaviviruses such as West Nile and dengue. One or more units will provide the capability to address scientific questions arising from the emergence of other emerging viral pathogens. In addition one or more units will focus on the emergence of viral-like prion agents typified by those associated with infectious neurologic diseases such as transmissible spongiform encephalopathies (TSE) in both humans and animals.

Those units dealing with conventional viruses must develop and maintain the capacity to quickly study new threats from emerging viruses and provide needed information in the areas of general virology, viral immunology, viral pathogenesis, and epidemiology of these agents. These units must demonstrate the ability to perform field studies to define the natural cycling of the virus in the environment. They should include experts in the study of arthropod-borne vectors and enzootic amplifying hosts. The capability to work on these agents will be demonstrated by establishing and maintaining a successful research program providing needed scientific information on viruses that have already emerged, particularly flaviviruses such as West Nile and dengue. An additional capacity to be developed by these units is the ability to analyze new, environmentally sound vector control tools and other strategies needed to intervene in the emergence and spread of arthropod-borne infectious diseases.

One or more units will focus on unconventional viral-like agents, primarily prions associated with infectious neurologic diseases such as transmissible spongiform encephalopathies (TSE) in both humans and animals. Laboratory studies show that there is a strong barrier to inter-species infection by TSE-associated prions. Nevertheless, the actual risk to humans posed by TSE-affected cattle or other animals remains unknown. In the U.S., there have been no documented cases of TSE in cattle, but other prion diseases are endemic in several western states. These units will determine factors effecting intra-species transmission of TSEs to humans and potential interventions for prevention or treatment of disease.

In the event of a public health threat, each unit will be required to respond by re-direction of its program. Therefore, it is envisioned that these units will implement, staff and maintain coordinated groups that can provide information needed to enhance the U.S. capacity to better predict, prevent, treat and control emerging viral diseases.

Studies envisioned include key elements of: the natural history and epidemiology of the agent, its replication and evolution, and its pathogenesis in animal and human hosts. This information would be used to develop and test prediction, prevention and control strategies utilizing newly developed public health tools such as vaccines and antiviral therapeutics.

BACKGROUND

The emergence of the AIDS epidemic, the appearance of hantavirus in the Southwestern U.S. and the spread of West Nile virus in the Northeastern U.S. demonstrate the vulnerability of the U.S. to emerging viruses. Two recent studies co-funded by NIAID (Institute of Medicine: Emerging Infections--Microbial Threats to Health in the United States, National Academy Press; and The U.S. Capacity to Address Tropical Infectious Disease Problems, National Academy Press) warned that the threat posed by disease-causing microbes is expected to intensify in coming years.

Factors influencing the emergence and distribution of infectious diseases in general include those associated with the microbial agent itself, the agent's hosts and vectors, and the environment in which agent and host interact. A number of US Government agencies support studies to obtain knowledge about the factors influencing emergence of viral agents. However, for many infectious diseases, the specific factors contributing to emergence are poorly understood. Nonetheless, knowledge of these factors is essential in planning strategies to prevent, treat, and control these diseases. The overall objective of this RFP is to address the needs not met by existing government supported projects, and obtain the relevant knowledge and appropriate public health tools needed for the NIH to be responsive to emerging viral pathogens.

The natural life cycle of many viruses is complex and in addition to the virus, may include one or more reservoirs or amplifying hosts, and often an arthropod vector. A change affecting the interaction of these fundamental elements might lead to the emergence or re-emergence of a viral disease. Natural or man-made changes to environmental factors typically impact on virus vectors or hosts. An example of the role of natural changes in the environment contributing to the emergence of disease is the 1993 appearance of hantavirus in the Southwestern U.S. It is thought that the virus in part emerged as a result of climatic and environmental conditions favorable for increased rodent populations. Man-made changes to the environment also lead to the emergence of disease. Historically, commerce has often brought new viruses, vectors, or hosts into an area. There have been several accounts of endemic viruses emerging and spreading as the result of such changes as: (a) development of dams and water projects resulting in altered water flow, (b) deforestation and changing land-use associated with the development of new communities, and (c) the introduction of new virus-amplifying hosts or the expansion of new vectors due to changing international trade. . A classic example is the spread of yellow fever in the western hemisphere in the 19th and early 20th century. Ongoing expansion of worldwide trade may facilitate the emergence of new viruses, or increase the spread of previously known viruses to a new receptive environment. Finally, viruses might emerge in new areas as the result of man's deliberate release of an agent by an act of bioterrorism.

In some instances, viruses might emerge as the result of selection of new genetic strains and variants with increased infectiousness, virulence or transmissibility. This has been well established as a cause for the emergence of new influenza outbreaks, and, in an analogous fashion, probably contributes to the emergence of other viruses particularly the bunyaviruses.

Major impediments in meeting these emerging virus threats are the formidable problems posed by the immediate need for input from multiple disciplines in response to an emerging disease threat. There is a need to design interdisciplinary teams with sufficient tools, approaches and model systems to help formulate coordinated strategies for anticipating, detecting, controlling, and preventing emergence or re-emergence of viral and viral-like agents.

Statement of Work
U.S. Based Collaboration In Emerging Viral and Prion Diseases
RFP NIH-NIAID-DMID-02-24

Independently and not as an agent of the Government, the Contractor shall furnish all necessary services, qualified professional and technical personnel, volunteer populations, materials, equipment, and facilities, not otherwise provided by the Government under the terms of this contract as needed to conduct the studies as set out below and as approved by the Project Officer.

Multi-project approaches are encouraged to develop broadly based, multi-disciplinary units. It is envisioned that at least one contract will be awarded per unit. An Offeror may submit proposals for more than one unit; however, proposals must be separated by unit(s). When appropriate, a prime contract Offeror may coordinate studies through the use of subcontracts with laboratories and clinical centers to provide competence in particular areas that complement the abilities available to the prime Offeror. An important feature of the multi-project approach is the synergy that results from collaborative efforts. NIAID encourages flexibility throughout the contract period regarding use of collaborators and choice of projects in order to continually incorporate new ideas and projects of the highest scientific merit.

Offerors are encouraged to propose projects within, but not limited to the general areas listed below. All projects should be focused to yield for the Government the information and public health tools helpful in prediction, prevention, treatment, or control of emerging viral diseases. Offerors should note that, at the direction of the Project Officer and/or the Contracting Officer, units must be capable of rapidly re-directing resources to address a potential urgent public health threat, such as a bioterrorism event. Each unit shall prepare and provide a plan showing its capability to quickly design, review and undertake such pilot projects.

Since other initiatives are available to support research on influenza, hepatitis, herpes viruses, papilloma viruses, respiratory syncytial virus, measles, and retroviruses, projects on these viruses should not be submitted.

NIAID intends to support at least two (2) units to address emerging viruses (see work statement items 1,2 and 5 below) and one or more units addressing prion and unconventional viral-like agents (see work statement items 3, 4 and 5 below). Note that all of the units shall be required to conduct work statement items 1, 2 and 5.

Specifically, the Contractor shall:

1. For the units dealing with studies on emerging, conventional viruses, establish and/or maintain a focused and coordinated research group with expertise in general virology, viral pathogenesis, molecular biology and viral immunology. The units will choose one or more emerging viral diseases as models to design and conduct studies that include, but are not limited to, those listed below. In this way, the units will develop and maintain the listed capability and expertise in the course of generating needed scientific information.
 - Establish and maintain the ability to rapidly isolate, cultivate, identify and characterize new viral diseases or recognized diseases emerging in new regions.
 - Establish and/or maintain animal models and cell culture systems to evaluate: the pathogenic potential of viruses, the immunologic response associated with disease progression and the immunologic basis and immune correlates of natural protective immunity. As designated by the Project Officer, further characterize and/or modify these models or develop other models to improve model utility. The contractor may be required to use animal models other than the one proposed if well-characterized animal models become available.
 - Maintain the ability to develop and utilize relevant assays to assess the immunologic status of humans and potentially important animal host species.
 - Maintain the ability to assess genetic strain variation and correlate these changes with factors influencing pathogenesis or emergence.
 - When designated by the Project Officer, perform pre-clinical, animal model-based evaluation of newly developed vaccines or drug therapies for emerging viruses.
 - At the specific request of the Project Officer, provision shall be made to obtain and preserve samples of viruses or animal tissues and fluids. Samples shall be sent, at the direction of the Project Officer, to another contractor or grantee that may perform additional experiments with, or analysis on, the samples. The Contractor shall cooperate or collaborate with other investigators as requested.

2. For the units dealing with studies on emerging, conventional viruses, establish and/or maintain a focused and coordinated research group to further our basic understanding of the epidemiology of emerging viral diseases. Include the expertise to study the ecologic and environmental factors influencing emergence, spread and distribution of emerging viral diseases threatening the U.S. The units will choose one or more emerging viral diseases as models to design and conduct studies that include, but are not limited to those listed below. In this way, the units will develop and maintain the listed capability and expertise in the course of generating needed scientific information.

- Establish a program to define the natural association of emerging viruses with their vectors or hosts, and their roles during maintenance and emergence of viruses. Within this program, attempt to determine if the emergence of a disease resulted from the influence of natural, man-made, or climate-induced environmental changes. Where possible an analysis of the predictive value of information from these studies should be performed.
- Establish the capacity and expertise needed to perform epidemiological studies in the field to quickly determine susceptible hosts and vectors that play an important role during emergence of disease.
- Expand and maintain the capacity to perform vector specific studies on: the ecology, biology, and physiology of important vector species and on the identification of bridge vectors that transmit viruses to humans. Analyze the biotic and abiotic elements of an ecosystem of interest to quantify the vector and reservoir species abundance, distribution, population structure, survivorship, food sources, predators, infection status, insecticide resistance status, etc. relative to a particular disease transmission process. Models should include habitat structure parameters and human density / distribution / and exposure parameters. An example of this would be study of the rodent, avian and mosquito species abundant in areas of the US where West Nile virus transmission occurs. Other emerging viral infections are equally valid as topics of study. Develop a database of information generated by these studies for later use by investigators who will develop and validate predictive models of disease transmission to humans.
- Establish and/or maintain the ability to perform molecular epidemiological studies to follow natural genetic strain variation.

3. For the units dealing with prions and unconventional viral-like agents, establish and/or maintain a focused and coordinated group with expertise in studies of Transmissible Spongiform Encephalopathies (TSEs) as infectious diseases. This should include expertise on animal diseases with the potential to transmit to humans. The units will choose one or more prion diseases as models to design and conduct studies that include, but are not limited to, those listed below. In this way, the units will develop and maintain the listed capability and expertise in the course of generating needed scientific information.

- Establish and maintain the ability to isolate, identify and characterize TSE agents that are new or that have transmitted to a new host.
- Establish and/or maintain animal models and cell culture systems to evaluate the potential for transmission (inter-and intra-species) and pathogenesis of TSE agents. Approaches shall include, but not be limited to evaluating the impact of factors such as PrP strain and host genotype. As designated by the Project Officer, further characterize and/or modify these models or develop other models to improve model utility. The contractor may be required to use animal models other than the one proposed if well-characterized animal models become available.
- Establish and/or maintain the ability to assess TSE agent strain variation and correlate these changes with factors influencing transmissibility, host range, and pathogenesis.
- Where needed, perform pre-clinical, animal model-based evaluation of newly developed prophylaxes or therapies for TSE infection and disease. These will likely involve identification and maintenance of suitable animal models of disease to allow studies of potential prevention/treatment therapies. Depending on the candidate, evaluation will include documentation of: dose/response, overall efficacy at preventing disease, safety, reactogenicity or toxicity, and the effect of the timing of administration relative to exposure.
- At the specific request of the Project Officer, provision shall be made to obtain and preserve samples of infectious material or other animal tissues and fluids. Samples shall be sent, at the direction of the Project Officer, to another contractor or grantee that may perform additional experiments with, or analysis on, the samples. Maintain a capacity to develop, analyze and distribute reagents, infectious material, molecular clones, and transgenic mice that will be needed by qualified investigators to facilitate overall research in TSE infections. The Contractor shall cooperate or collaborate with other investigators as requested.

4. For the one units dealing with prions and unconventional viral-like agents, implement a systematic approach to furthering our understanding of the ecologic and environmental factors influencing emergence, spread and distribution of TSEs threatening the U.S. Implement a systematic approach towards furthering our understanding of the basic epidemiology and clinical aspects of these diseases. The units will choose one or more prion diseases as models to design and conduct studies that include, but are not limited to those listed below. In this way, the units will develop and maintain the listed capability and expertise in the course of generating needed scientific information.

- Establish research focusing on the natural association of a TSE with its host(s), and their roles during maintenance and emergence of TSEs.
- Evaluate and define the effect on the intra- and inter-species spread of TSEs of: natural, man-made, or climate-induced environmental change; alterations in host population density and distribution; public health practices, altered social/behavioral practices, or modern technological developments. Where possible an analysis of the predictive value of information from these studies should be performed.
- Develop, when needed, the epidemiologic tools to implement surveillance of infection in relevant populations.
- Implement incidence/prevalence surveys in the populations to provide the necessary background information to conduct future prevention and/or therapeutic trials.
- Implement a system to collect and characterize TSE infectious material derived from the unit's research efforts studies.
- Establish the capacity and expertise needed to perform epidemiological studies in the field to quickly determine susceptible hosts that play an important role during emergence of disease.
- Develop a program to help improve surveillance of TSEs. The primary aim will not be surveillance per se, but research within this objective, such as the development of improved diagnostic reagents and assays. Develop where needed, approaches for the more effective diagnosis
- Establish strategic national and international collaborations needed to quickly determine and analyze the issues relevant to the natural emergence of TSEs, and to determine potential targets for preventative and therapeutic agents.

5. For all units, develop and implement an organizational and administrative plan. Assume responsibility for: the detailed planning, conduct, and reporting of all studies and the management of all resulting data, including transmission, storage, confidentiality, retrieval, validation, statistical analysis, and publication.

- Establish and manage laboratory facilities to support the various studies.
- Supervise, coordinate, and perform the tasks outlined in the Work Statement. Formulate a balanced budget to perform the tasks outlined in the work statement.
- At the direction of the Project Officer and/or the Contracting Officer, rapidly re-direct resources to address a potential urgent public health threat, such as a bioterrorism event. Each unit will provide a plan showing its capability to quickly design, review and undertake such pilot projects.
- Conduct at least one meeting per year to discuss results and future plans with key investigators and subcontractors within the study consortia. At the Project Officers request, conduct conference telephone calls.
- At the Project Officers need, send representatives to attend and participate in one 2 day meeting per year in Bethesda to discuss results and future plans. The purpose of these meetings will be to share data and allow the transmittal of encouraging approaches to other scientists.
- Conduct work in accordance with the Biosafety in Microbiological and Biomedical Laboratories guidelines, and NIH guidelines for animal care and Human use. All the units should have the capacity to study these agents at Biosafety Level 3.
- Establish electronic message and document transfer capability with the Project Officer. The NIAID is connected to the INTERNET and uses IBM-compatible computers.
- Establish within each unit a training component to help educate pre and postdoctoral investigators.

Notes To Offerors
U.S. Based Collaboration In Emerging Viral and Prion Diseases
NIH-NIAID-DMID-02-24

1. Offeror should document previous experience with related research, and demonstrate the ability to perform these tasks by describing ongoing projects. **[This note relates to all work statement items.]**
2. These studies may include the characterization and definition of the model system(s) in terms of the disease pathogenesis and host response. The model system(s) employed should have features similar to the corresponding infection in humans and these should be described. The pathologic and immunologic aspects of the model in association with virus infection should be discussed and related to the ability to use this model to predict clinical effectiveness of experimental therapeutics. **[This note relates to work statement items #1 and #3.]**
3. A copy of the applicable Biosafety guidelines may be obtained from NIAID upon request. It is available at <http://www.nih.gov/od/ors/ds/pubs/bmbf/>. These guidelines will apply to all studies supported by this RFP. The experience of the Offeror in working with potential biohazards, as well as toxic chemicals and radioisotopes, should be addressed. Relevant safety procedures at the institution should be discussed. In addition, procedures for the care of experimental animals should be discussed. **[This note relates to work statement item #5.]**
4. It is understood that no one institution may have all the requisite expertise to perform all aspects of this requirement. Therefore, Offerors are welcome to propose performance of the effort by multiple collaborating institutions, using subcontracts or other formal arrangements.
5. Unfortunately, gaps in our knowledge of emerging viruses remain in multiple areas, and there are limited numbers of groups studying these viruses. For some viruses, a relatively large amount of basic information exists, and focused research and detailed experimental strategies can be formulated. However, other emerging viruses have only recently been implicated as a disease threat. The goals of appropriate, state-of-the-art studies for those viruses will be less sophisticated, but no less important.
6. Costs for travel to required meetings should be included in the business proposal. Indicate the number of travelers, identify the individual's contract role, destinations, duration of trips, reason(s) for the travel and the benefit(s) to be gained by the contract as a result of the travel.
7. In the event of an urgent public health threat that demands re-direction of funds and resources, additional funds may or may not be provided to the unit.
 - a. As a multi-center (i.e. prime contractor with subcontractors) approach is anticipated for response to this RFP, the organizational and administrative plan should clearly identify the role of subcontractors and provide for a clear plan of communication and project interactions. Letters of willingness to participate/collaborate must accompany the proposal. Potential subcontractors may submit such letters to more than one Offeror. Although other government agencies are excluded from receiving funds either directly or indirectly from this contract activity they are not excluded from collaborating in any project at their own expense. Subcontractors may be added or deleted during the contract award period with the prior approval of the Project Officer and Contracting Officer.
 - b. A two page Biosketch of all proposed professional personnel should be included in the technical proposal.

Reporting Requirements
U.S. Based Collaboration In Emerging Viral and Prion Diseases
RFP NIH-NIAID-DMID-02-24

Each contractor (unit) shall be required to prepare and submit semi-annual technical progress reports as indicated below. Other specialized project reports may be required on an as-needed basis by the Project Officer.

REPORT TYPE	NUMBER OF COPIES	ADDRESSEE	WHEN DUE
Semi-Annual Progress Report	Three (3)	NIAID Project Officer Bethesda, Maryland	Within 15 calendar days of the end of each reporting period
Semi-Annual Progress Report	One (1)	NIAID Contracting Officer Bethesda, Maryland	Within 15 calendar days of the end of each reporting period
Final Progress Report	Three (3)	NIAID Project Officer Bethesda, Maryland	Upon Contract Completion
Final Progress Report	One (1)	NIAID Contracting Officer Bethesda, Maryland	Upon Contract Completion

PART I - THE SCHEDULE

SECTIONS B - H -- UNIFORM CONTRACT FORMAT - GENERAL

A Sample Uniform Contract Format may be found at the following website:

<http://www4.od.nih.gov/ocm/contracts/rfps/sampkt.htm>

[Disregard SECTION I and J of this sample. Those SECTIONS have been incorporated as part of this RFP.]

PART II – CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING PAGES CONTAIN A LISTING(S) OF GENERAL CLAUSES WHICH WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSES LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP.

BECAUSE THIS IS A STREAMLINED RFP, ARTICLES I.2. AND I.3., WHICH IDENTIFY ANY AUTHORIZED ADDITIONS, SUBSTITUTIONS AND/OR MODIFICATIONS TO THE GENERAL CLAUSES, WILL BE BASED ON THE TYPE OF CONTRACT/CONTRACTOR AND WILL BE DETERMINED DURING NEGOTIATIONS.

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT – FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this URL: <http://www.arnet.gov/far/>.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CHAPTER 1) CLAUSES

FAR

<u>Clause No.</u>	<u>Date</u>	<u>Title</u>
52.202-1	Oct 1995	Definitions
52.203-3	Apr 1984	Gratuities (Over \$100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over \$100,000)
52.203-6	Jul 1995	Covenant Against Contingent Fees (Over \$100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures (Over \$100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over \$100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over \$100,000)
52.203-12	Jun 1997	Limitation on Payments to Influence Certain Federal Transactions (Over \$100,000)
52.204-4	Aug 2000	Printing/Copying Double-Sided on Recycled Paper (Over \$100,000)
52.209-6	Jul 1995	Protecting the Governments Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over \$25,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over \$100,000)
52.215-8	Oct 1997	Order of Precedence – Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over \$500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over \$100,000)
52.215-15	Dec 1998	Pension Adjustments and Asset Reversions
52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) Other Than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.216-7	Mar 2000	Allowable Cost and Payment
52.216-8	Mar 1997	Fixed Fee
52.216-11	Apr 1984	Cost Contract - No Fee

52.219-8	Oct 2000	Utilization of Small Business Concerns (Over \$100,000)
52.219-9	Oct 2001	Small Business Subcontracting Plan (Over \$500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over \$500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over \$100,000) (NOTE: The dollar amount in paragraph (a) of this clause is \$0 unless otherwise specified in the contract.)
52.222-3	Aug 1996	Convict Labor
52.222-7	Feb 1988	Withholding of Funds
52.222-8	Feb 1988	Payrolls and Basic Records
52.222-12	Feb 1988	Contract Termination – Debarment
52.222-26	Feb 1999	Equal Opportunity
52.222-35	Apr 1998	Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Jan 1999	Employment Reports on Disabled Veterans and Veterans of the Vietnam Era
52.223-3	Jan 1997	Hazardous Material Identification and Material Safety Data, Alternate I (Jul 1995)
52.223-6	May 2001	Drug-Free Workplace
52.223-14	Oct 2000	Toxic Chemical Release Reporting
52.225-1	Feb 2000	Buy American Act - Balance of Payments Program – Supplies
52.225-13	Jul 2000	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over \$100,000)
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (NOTE: In accordance with FAR 27.303 (a) (2), paragraph (f) is modified to include the requirements in FAR 27.303 (a) (2) (i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Jun 1987	Rights in Data – General
52.229-3	Jan 1991	Federal, State and Local Taxes (Over \$100,000)
52-232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	Jun 1996	Interest (Over \$100,000)
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	May 2001	Prompt Payment
52.232-34	May 1999	Payment by Electronic Funds Transfer--Other Than Central Contractor Registration

52.233-1	Dec 1998	Disputes
52.233-3	Aug 1996	Protest After Award
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2001	Penalties for Unallowable Costs (Over \$500,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over \$100,000)
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	Aug 1998	Subcontracts *If written consent to subcontract is required, the identified subcontracts are listed in Article B, Advance Understandings.
52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B., Advance Understandings.
52.244-5	Dec 1996	Competition in Subcontracting (Over \$100,000)
52.245-5	Jan 1986	Government Property (Cost-Reimbursement, Time and Material, or Labor Hour Contract)
52.246-23	Feb 1997	Limitation of Liability (Over \$100,000)
52.249-6	Sep 1996	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES

<u>HHSAR Clause No.</u>	<u>Date</u>	<u>Title</u>
352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.232-9	Apr 1984	Withholding of Contract Payments
352.233-70	Apr 1984	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings
352.270-5	Apr 1984	Key Personnel
352.270-6	Jul 1991	Publication and Publicity

[END OF GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH
AND DEVELOPMENT CONTRACT – Rev. 05/2001]

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following Attachments are provided in full text with this Solicitation:

PACKAGING AND DELIVERY OF PROPOSALS (Attached to this listing)

HOW TO PREPARE AN ELECTRONIC PROPOSAL: (Attached to this listing)

PROPOSAL INTENT RESPONSE SHEET [SUBMIT ON/BEFORE: January 15, 2002] (Attached to this listing)

[NOTE: Your attention is directed to the "Proposal Intent Response Sheet". If you intend to submit a proposal, you must complete this form and return it to this office via fax or e-mail on or before the date identified above. The receipt of this form is critical as it contains information essential for CMB's coordination of the electronic submission and review of proposals.]

RFP FORMS AND ATTACHMENTS:

THE RFP FORMS/ATTACHMENTS LISTED BELOW ARE AVAILABLE IN A VARIETY OF FORMATS AND MAY BE VIEWED OR DOWNLOADED DIRECTLY FROM THIS SITE:

<http://www.niaid.nih.gov/contract/ref.htm>

APPLICABLE TO TECHNICAL PROPOSAL (INCLUDE THESE DOCUMENTS/FORMS WITH YOUR TECHNICAL PROPOSAL):

- Technical Proposal Cover Sheet
- Technical Proposal Cost Information
- Summary of Related Activities
- Government Notice for Handling Proposals

APPLICABLE TO BUSINESS PROPOSAL (INCLUDE WITH YOUR BUSINESS PROPOSAL):

- NIH-2043, Proposal Summary and Data Record
- Small Business Subcontracting Plan Format *[if applicable]*
- Breakdown of Proposed Estimated Cost (plus fee/profit) and Labor Hours
- Offeror's Points of Contact

TO BECOME CONTRACT ATTACHMENTS (INFORMATION ONLY):

- NIH (RC)-4: Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts
- Instructions for Completing Form NIH-2706
- NIH (RC)-7: Procurement of Certain Equipment, (OMB Bulletin 81-16)
- Safety and Health, HHSAR Clause 352.223-70
- Report of Government Owned, Contractor Held Property

PACKAGING/DELIVERY/ELECTRONIC SUBMISSION OF THE PROPOSAL

Listed below are delivery instructions for the submission of both PAPER and ELECTRONIC COPIES of your proposal.

PAPER SUBMISSION: The paper copy is the official copy for recording timely receipt of proposals.

You are required to submit one original paper copy of your proposal along with the number of extra copies required below.

ELECTRONIC SUBMISSION: In addition to the paper submission, you are required to submit your proposal electronically through the CRON (Contracts Review Online) in accordance with the instructions provided below. If you experience difficulty or are unable to transmit, you should submit your proposal on a CD-Rom or ZipDisk by an express delivery service. We can then upload your proposal into the electronic system. You must certify that both the original paper and electronic versions of the proposal are identical.

SUBMISSION OF PROPOSALS BY FACSIMILE IS NOT ACCEPTABLE.

Shipment and marking of paper copies shall be as indicated below:

A. EXTERNAL PACKAGE MARKING:

In addition to the address cited below, mark each package as follows:

"RFPNIH-NIAID-DMID-02-24 TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

B. NUMBER OF COPIES:

The number of copies required of each part of your proposal are as specified below.

Technical Proposal: One (1) unbound signed original and five (5) unbound copies. Ten (10) copies of any materials not available electronically (i.e. SOPs, Pertinent Manuals, Non-scannable Figures or Data, and Letters of Collaboration/Intent, etc.).

Business Proposal: One (1) unbound signed original and 5 unbound copies.

C. PAPER COPIES and CD-Rom or ZipDisk to:

If Hand Delivery or Express Service	If using U.S. Postal Service
Contract Specialist Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230 Bethesda, Maryland 20817	Contract Specialist Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230, MSC 7612 Bethesda, Maryland 20892-7612

NOTE: All material sent by Federal Express or other courier service should be sent to the Hand Delivery Address.

NOTE: The U.S. Postal Service's "Express Mail" does not deliver to the hand delivered (20817 zip code) address. Any package sent to this address via this service will be held at a local post office for pick-up. THE GOVERNMENT IS NOT RESPONSIBLE FOR PICKING UP ANY MAIL AT A LOCAL POST OFFICE. If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal," in accordance with HHSAR 352.215-70, Late Proposals and Revisions (NOV 1986).

HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL

PAGE LIMITS -- THE **TECHNICAL PROPOSAL** IS LIMITED TO NOT-TO-EXCEED 100 PAGES [INCLUDING: Appendices, Attachments, Operating Manuals, Non-Scannable Figures or Data, Letters of Intent, etc.]. ANY PORTIONS OF YOUR PROPOSAL NOT AVAILABLE ELECTRONICALLY ARE ALSO CONSIDERED TO BE INCLUDED IN THE TOTAL PAGE LIMITATION. PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE READ OR EVALUATED.

Note that although no page limit has been placed on the **Business Proposal**, Offerors are encouraged to limit its content to only those documents necessary to provide adequate support for the proposed costs.

ELECTRONIC SUBMISSION – To submit a proposal electronically under this RFP, Offerors will need to prepare the proposal on a word processor or spreadsheet program (for the business portion) and convert them to Adobe Acrobat Portable Document Format (.pdf). THE TECHNICAL PROPOSAL AND BUSINESS PROPOSAL MUST BE CONTAINED ON SEPARATE FILES which must be identified as either TECHNICAL or BUSINESS and include some recognizable portion of the ORGANIZATION NAME.

Please note that the electronic submission does not replace the requirement to submit a signed, unbound original paper copy of both your Technical and Business Proposal, along with any required unbound duplicate copies. These paper originals should be mailed or hand-delivered to the address provided in this attachment and must be received on/before the closing date and time.

There is no limit to the size (MB) of the two electronic PDF files to be submitted; however, the size of the technical proposal is limited to the page limitation language outlined above. For purposes of assessing compliance with the page count, technical proposals will be viewed using the print function of the Adobe Acrobat Reader, Version 4.0 (or higher).

Formatting Requirements:

- Do not embed sound or video (e.g., MPEG) files into the proposal documents. The evaluation system does not have the capability to read these files.
- Keep graphics embedded in documents as simple as possible. Complex graphics require longer periods for the computers used in the evaluation system to draw, and redraw these figures and scrolling through the document is slowed significantly.
- Type density and size must be 10 to 12 points. If constant spacing is used, there should be no more than 15 cpi, whereas proportional spacing should provide an average of no more than 15 cpi. There must be no more than six lines of text within a vertical inch. Margins must be set to 1 inch around.
- Limit colors to 256 colors at 1024 x 768 resolution; avoid color gradients.
- Simplify the color palette used in creating figures.
- Be aware of how large these graphics files become. Large files are discouraged.
- Limit scanned images as much as possible.
- Limit appendices and attachments to relevant technical proposal information (e.g., SOPs, pertinent manuals, non-scannable figures or data, resumes, letters of commitment/intent).

SUBMISSION OF “PROPOSAL INTENT TO RESPOND SHEET”:

Approximately TWO weeks prior to the due date of the proposals, all Offerors who submitted a “Proposal Intent Response Sheet” will be provided with specific electronic access information and electronic proposal transmission instructions. For this reason, it is imperative that all Offerors who are intending to submit a proposal in response to this RFP contact the Contract Specialist identified in this RFP and complete and submit the attached “Proposal Intent Response Sheet” by the date provided on that Attachment.

CREATE ADOBE PDF ONLINE -- Adobe will allow you to create 5 documents on a trial for free. If you want to use the site regularly it costs \$10/month or \$100/year. Please link to the following URL for information:

<https://createpdf.adobe.com/index.pl/3847995518.39272?BP=IE>

LOG-IN / TRANSMISSION INSTRUCTIONS:

1. Log-in Site: <https://apps.niaid.nih.gov/ecms/cmsproposal/>
 2. Log-in Name: Will be provided by the Contract Specialist.
 3. Log-in Password: Will be provided via telephone by the Contract Specialist after Log-in Name is provided.
4. Procedure -- When your proposal is completed and converted to a PDF file using Adobe Acrobat, it is ready to be transmitted electronically. You must upload separate Technical and Business Proposal Files. It is recommended that proposals be transmitted a few days before the due date so that you will have sufficient time to overcome any transmission difficulties.
- You must have Explorer 3.1 or higher.
 - It is essential that you use antiviral software to scan all documents.
 - Click on "Sign On" and enter your log-in name and password.
 - Click on "Browse" to locate your saved files on your computer.
 - Click on "Upload Proposal" after you have located the correct file.
 - After a file is uploaded, a link to the file will appear under "Upload Files" at the bottom of the screen. Click on that link to view the uploaded file.
 - If you experience difficulty in accessing your documents, please contact the appropriate NIH contracts office immediately.
 - If you wish to revise your proposal before the closing date and time, simply log in again and re-post.

USER ACCESS TO THE POSTING SITE WILL BE DENIED AFTER THE RFP CLOSING DATE AND TIME PROVIDED WITH THIS RFP OR ITS MOST RECENT AMENDMENT(S).

PROPOSAL INTENT RESPONSE SHEET

RFP: NIH-NIAID-DMID-02-24

RFP Title: US Based Collaboration in Emerging Viral and Prion Diseases

Please review the attached Request for Proposal. Furnish the information requested below and return this page by Tuesday, January 15, 2002. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

Since your proposal will be submitted electronically, please include the name and e-mail of the individual to whom the electronic proposal instructions, login code, and password should be provided.

☐ DO INTEND TO SUBMIT A PROPOSAL

☐ DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASON(S):

Company/Institution Name (print): _____

Address (print): _____

Project Director's Name (print): _____

Title (print): _____

Signature/Date: _____

Telephone Number and E-mail Address (print clearly):

***Name of individual to whom electronic proposal instructions should be sent:**

Name: _____

Title: _____

E-Mail Address: _____

Telephone Number: _____

Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):

(Continue list on a separate page if necessary)

RETURN VIA FAX OR E-MAIL TO:

CMB, NIAID, NIH

Room 2230

6700-B Rockledge Drive, MSC 7612

Bethesda, MD 20892-7612

Attn: Paul D. McFarlane

RFP NIH-NIAID-DMID-02-24

FAX# (301) 480-5253

Email : pm24v@nih.gov

PART IV – REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

Representations, Certifications, and Other Statements of Offerors or Quoters (Negotiated).

1. REPRESENTATIONS AND CERTIFICATIONS

The Representations and Certifications required by this particular acquisition can be accessed electronically from the INTERNET at the following address:

<http://rcb.nci.nih.gov/forms/rcneg.pdf>

If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE THE REPRESENTATIONS AND CERTIFICATIONS AND SUBMIT THEM AS PART OF YOUR BUSINESS PROPOSAL.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION [FAR Clause 52.215-1 (May 2001)]

(a) *Definitions.* As used in this provision--

Discussions are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"In writing", "writing", or *"written"* any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"Proposal modification" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"Proposal revision" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"Time," if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations.* If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals.* (1) Unless other methods (*e.g.*, electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--

- (i) The solicitation number;
- (ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
- (iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;
- (iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and
- (v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) *Submission, modification, revision, and withdrawal of proposals.* (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

- (ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it

is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

- (1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or
- (2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or
- (3) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government will be considered at any time it is received and may be accepted.

- (iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.
- (iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.
- (v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) *Offer expiration date.* Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

[Note: In accordance with HHSAR 352.215-1, the following paragraph (e) is substituted for the subparagraph (e) of the provision at FAR 52.215-1.]

(e) *Restriction on disclosure and use of data.* (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

- (2) In addition, the offeror should mark each page of data it wishes to restrict with the following statement:

“Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation.”

- (3) Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

- (f) *Contract award.* (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

- (2) The Government may reject any or all proposals if such action is in the Government's interest.

- (3) The Government may waive informalities and minor irregularities in proposals received.

- (4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

- (5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

- (6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

- (7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

- (8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.
- (9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.
- (10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.
- (11) The Government may disclose the following information in post-award debriefings to other offerors:
 - (i) The overall evaluated cost or price and technical rating of the successful offeror;
 - (ii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
 - (iii) A summary of the rationale for award; and
 - (iv) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(End of Provision)

Alternate I (October 1997). As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

a. NAICS CODE AND SIZE STANDARD

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

- (1) The North American Industry Classification System (NAICS) code for this acquisition is 54171.
- (2) The small business size standard is 500 or fewer employees.

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

b. TYPE OF CONTRACT AND NUMBER OF AWARD(S)

It is anticipated that multiple awards will be made from this solicitation and that the awards will be made on/about September 27, 2002.

It is anticipated that the awards from this solicitation will be a multiple-year cost reimbursement - completion type contract with a seven-year period and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

c. ESTIMATE OF EFFORT AND FUNDING

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the estimate of effort to be approximately 1,260 percent of Professional effort and 1,050 of Support effort. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes. Further, NIAID estimates that approximately \$23 million will be available for these contracts over their 7-year performance periods.

d. COMMITMENT OF PUBLIC FUNDS

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

e. COMMUNICATIONS PRIOR TO CONTRACT AWARD

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

f. RELEASE OF INFORMATION

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

g. COMPARATIVE IMPORTANCE OF PROPOSALS

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are [significantly more important than cost or price/approximately equal to cost or price/significantly less important than cost or price]. The relative importance of the evaluation factors is specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

h. PREPARATION COSTS

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

i. SERVICE OF PROTEST (AUGUST 1996) - FAR 52.233-2

- (a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Brenda J. Velez
Contracting Officer
Contract Management Branch, DEA
National Institute of Allergy and Infectious Diseases
6700-B Rockledge Drive, Room 2230, MSC 7612
BETHESDA MD 20892-7612

- (b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

j. **LATE PROPOSALS AND REVISIONS, HHSAR 352.215-70**

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors—Competitive Acquisition, a proposal received after the date specified for receipt may be considered if it offers significant cost or technical advantages to the Government; and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision)

i. **USE OF INTERNET WEB SITE ADDRESSES (URLs) IN PROPOSALS**

Unless otherwise specified or required in NIAID solicitations, internet Web Site addresses (URLs) may not be used to provide information necessary to the conduct of the review of the proposal. Direct access to an Internet site by a Reviewer who is examining and reviewing the proposal on behalf of the NIAID could compromise their anonymity during the review process. If a URL contains information pertinent to the proposal content, the offeror must provide access to the website via a temporary website portal which allow reviewers the capability to view and interact with the site.

The proposal must clearly identify the URLs to be accessed and the procedure for accessing the temporary website portal. Access must not require the identity of the individual making this access.

2. INSTRUCTIONS TO OFFERORS

GENERAL INSTRUCTIONS

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

(1) Contract Type and General Clauses

It is contemplated that multiple cost-reimbursement - completion type contracts will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(2) Authorized Official and Submission of Proposal

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

(3) Proposal Summary and Data Record (NIH-2043)

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See Section J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD).

(4) Separation of Technical and Business Proposals

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Attachment entitled, TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS.) However, the technical proposal should **not** include pricing data relating to individual salary information, indirect cost rates or

amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) Alternate Proposals

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

(6) Evaluation of Proposals

The Government will evaluate technical proposals in accordance with the criteria set forth in PART IV, SECTION M of this RFP.

(7) Potential Award Without Discussions

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

(8) Use of the Metric System of Measurement

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(9) Care of Live Vertebrate Animals

- a. The following notice is applicable when contract performance is expected to involve care of live vertebrate animals:

Notice to Offerors of Requirement for Adequate Assurance of Protection of Vertebrate Animal Subjects - (SEPTEMBER 1985)

The Public Health Service (PHS) Policy on Human Care and Use of Laboratory Animals establishes a number of requirements for research activities involving animals. Before a PHS award may be made to an applicant organization, the organization shall file, with the Office of Extramural Research (OER), Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), PHS, a written Animal Welfare Assurance which commits the organization to comply with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources. In accordance with the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, applicant organizations must establish a committee, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. No PHS award involving the use of animals shall be made unless the Animal Welfare Assurance has been approved by OER. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Animal Welfare Assurance is

required. The Contracting Officer will request that OER, OLAW negotiate an acceptable Animal Welfare Assurance with those Contractor(s). For further information, OER, OLAW, may be contacted at Rockledge Center I - Suite 1050, 6705 Rockledge Drive, Bethesda, MD 20817, (301) 496-7163, ext 234. FAX copies are of the PHS Policy are available at (301) 402-2803. This policy is also available on the internet at <http://www.grants.nih.gov/grants/olaw/olaw.htm>.

b. If an Animal Assurance is already in place, the offeror's proposal shall include:

- The Animal Welfare Assurance number.
- The date last certified by OLAW. (i.e. assurance letter from OLAW)
- Evidence of recent AAALAC Accreditation.

(10) Obtaining and Disseminating Biomedical Research Resources

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a conditions of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

This policy, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090]) will be included in any contract awarded from this solicitation. It can be found at the following website: <http://ott.od.nih.gov/NewPages/64FR72090.pdf>.

(11) Privacy Act (Treatment of Proposal Information)

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the General Accounting Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

(12) Selection of Offerors

- a) The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.
- b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.
- c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.
- d) If the Government intends to conduct discussions prior to awarding a contract-

- (1) Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

- (2) The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is NIAID's policy to conduct discussions with all offerors in the competitive range, NIAID reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected sources in accordance with HHSAR 315.370.

- e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.
- f) The NIAID reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet NIAID requirements. Synopses of awards exceeding \$25,000 will be published in the Commerce Business Daily.

(13) Reimbursement of Costs for Independent Research and Development Projects (Commercial Organizations Only)

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. This support is provided in the form of contracts and grants totaling approximately 7 billion dollars annually. PHS has established effective, time tested and well recognized and accepted procedures for stimulating and supporting this independent research by selecting from multitudes of proposals those research projects most worthy of support within the constraints of its appropriations. The reimbursement of independent research and development costs not incidental to product improvement, through the indirect cost mechanism, would circumvent this competitive process.

To ensure that all research and development projects receive similar and equal consideration, all offerors may compete for direct funding for independent research and development projects they consider worthy of support by submitting those projects to the appropriate Public Health Service grant and/or contract office for review. Since these projects may be submitted for direct funding, the successful offeror agrees that no costs for any independent research and development project, including applicable indirect costs, will be claimed under any contract resulting from this solicitation.

(14) Institutional Responsibility Regarding Conflicting Interests of Investigators

EACH INSTITUTION MUST:

- (a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.
- (b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.
- (c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.
- (d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.
- (e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.
- (f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.
- (g) Certify, in each application/proposal for funding to which the regulations applies, that:
 - 1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;

- 2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;
- 3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and
- 4) the Institution will otherwise comply with the regulations.

INSTITUTIONAL MANAGEMENT OF CONFLICTING INTERESTS

- (a) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.**

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

- (i) public disclosure of significant financial interests;
 - (ii) monitoring of research by independent reviewers;
 - (iii) modification of the research plan;
 - (iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
 - (v) divestiture of significant financial interests; or
 - (vi) severance of relationships that create actual or potential conflicts of interests.
- (b) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

(15) Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: <http://www.arnet.gov/far/>.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

- a) Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991).
- b) Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).
- c) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).
- d) Pre-award On-Site Equal Opportunity Compliance Evaluation, (Over \$10,000,000), FAR Clause 52.222-24, (February 1999).

TECHNICAL PROPOSAL INSTRUCTIONS

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

(1) Technical Discussions

The technical discussion included in the technical proposal should respond to the items set forth below:

a) Statement of Work

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

b) Personnel

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

(1) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

(2) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

- The specific items or expertise they will provide.
- Their availability to the project and the amount of time anticipated.
- Willingness to act as a consultant.
- How rights to publications and patents will be handled.

(4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

(2) Technical Evaluation

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria (SEE SECTION M).

(3) Additional Technical Proposal Information

- a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.
- b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

(4) Other Considerations

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

- a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.
- b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

- c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.
- d) Other factors you feel are important and support your proposed research.
- e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

BUSINESS PROPOSAL INSTRUCTIONS

(1) Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

(2) Proposal Cover Sheet

The following information shall be provided on the first page of your pricing proposal:

1. Solicitation, contract, and/or modification number;
2. Name and address of Offeror;
3. Name and telephone number of point of contact;
4. Name, address, and telephone number of Contract Administration Office, (if available);
5. Name, address, and telephone number of Audit Office (if available);
6. Proposed cost and/or price; profit or fee (as applicable); and total;
7. The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.
8. Date of submission; and
9. Name, title and signature of authorized representative.

This cover sheet information is for use by offerors to submit information to the Government when cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not considered cost or pricing data, and shall not be certified in accordance with FAR 15.406-2.

(3) Information Other than Cost or Pricing Data

- a) The information submitted shall consist of data to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., information to support an analysis of material costs (when sufficient information on labor and overhead rates is already available), or information on prices and quantities at which the offeror has previously sold the same or similar items.

Any information submitted must support the price proposed. Include sufficient detail or cross references to clearly establish the relationship of the information provided to the price proposed. Support any information provided by explanations or supporting rational as needed to permit the Contracting Officer and authorized representative to evaluate the documentation.

[Unless otherwise stated in this solicitation, the information may be submitted in the offeror's own format.]

- b) The information submitted shall be at the level of detail described below.

1. **Direct Labor**

Provide a time-phased yearly breakdown of labor hours, rates, and cost by appropriate category. Key personnel will be separately estimated as above and identified. Give the basis for the estimates in each case.

2. **Materials**

Provide a consolidated price summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.).

3. Subcontracted Items

Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over \$550,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

4. Raw Materials

Consists of material in a form or state that requires further processing. Provide priced quantities of items required for the proposal.

5. Purchased Parts

Includes material items not covered above. Provide priced quantities of items required for the proposal.

6. Fringe Benefits

Show fringe benefits as a separate line item. Include the rate(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or institutional guidelines.

7. Indirect Costs

Indicate how offeror has computed and applied offeror's indirect costs, including cost breakdowns, and provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation. Where a rate agreement exists, provide a copy.

8. Special Equipment

If direct charge, list any equipment proposed including description, price, quantity, total price, purchase or lease, and the basis for pricing.

9. Travel

Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.

10. Other Costs

List all other costs not otherwise included in the categories described above (e.g., computer services, consultant services) and provide basis for pricing.

To assist in the preparation of future cost estimates, the Projected Consumer Price Index may be accessed at: <http://rcb.nci.nih.gov/forms/cpi.htm>

(4) Cost and Pricing Data

1. General Instructions

A. You must provide the following information on the first page of your pricing proposal:

- (1) Solicitation, contract, and/or modification number;
- (2) Name and address of offeror;
- (3) Name and telephone number of point of contact;
- (4) Name of contract administration office (if available);
- (5) Type of contract action (that is, new contract, change order, price revision/re-determination, letter contract, unpriced order, or other);

- (6) Proposed cost; profit or fee; and total;
 - (7) Whether you will require the use of Government property in the performance of the contract, and, if so, what property;
 - (8) Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;
 - (9) The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR 15.403-5(b)(1) and Table 15-2. By submitting this proposal, we grant the Contracting Officer and authorized representative(s) the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price;
 - (10) Date of submission; and
 - (11) Name, title and signature of authorized representative.
- B. In submitting your proposal, you must include an index, appropriately referenced, of all the cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.
 - C. As part of the specific information required, you must submit, with your proposal, cost or pricing data (that is, data that are verifiable and factual and otherwise as defined at FAR 15.401). You must clearly identify on your cover sheet that cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including--
 - (1) The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and
 - (2) The nature and amount of any contingencies included in the proposed price.
 - D. You must show the relationship between contract line item prices and the total contract price. You must attach cost-element breakdowns for each proposed line item, using the appropriate format prescribed in the "Formats for Submission of Line Item Summaries" section of this table. You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.
 - E. When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost.
 - F. Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.
 - G. If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.
 - H. As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406-2, submit a Certificate of Current Cost or Pricing Data.

2. **Cost Elements**

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

- A. **Materials and services.** Provide a consolidated priced summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.). Include raw materials, parts, components, assemblies, and services to be produced or

performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR 15.403-4. Submit the subcontractor cost or pricing data as part of your own cost or pricing data as required in paragraph 2.A.(2) of this table. These requirements also apply to all subcontractors if required to submit cost or pricing data.

- (1) *Adequate Price Competition.* Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.403-4 priced on the basis of adequate price competition. For interorganizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR 31.205-26(e)).
 - (2) *All Other.* Obtain cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR 15.403-4 and not otherwise exempt, in accordance with FAR 15.403-1(b) (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the lower of either \$10,000,000 or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor's proposed price. The Contracting Officer may require you to submit cost or pricing data in support of proposals in lower amounts. Subcontractor cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime contractor's Certificate of Current Cost or Pricing Data. The prime contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For interorganizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's cost or pricing data is required as described in this paragraph, it must be included along with your own cost or pricing data submission, as part of your own cost or pricing data. You must also submit any other cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.
- B. **Direct Labor.** Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish bases for estimates.
- C. **Indirect Costs.** Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.
- D. **Other Costs.** List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.
- E. **Royalties.** If royalties exceed \$1,500, you must provide the following information on a separate page for each separate royalty or license fee:
- (1) Name and address of licensor.
 - (2) Date of license agreement.
 - (3) Patent numbers.
 - (4) Patent application serial numbers, or other basis on which the royalty is payable.
 - (5) Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
 - (6) Percentage or dollar rate of royalty per unit.
 - (7) Unit price of contract item.
 - (8) Number of units.

(9) Total dollar amount of royalties.

(10) If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.204 and 31.205-37).

F. **Facilities Capital Cost of Money.** When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB-CMF and show the calculation of the proposed amount (see FAR 31.205-10).

3. **Formats for Submission of Line Item Summaries**

The detailed breakdown shall be in the format as shown on the form **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours** (SECTION J, List of Attachments). For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished.

To assist in the preparation of future cost estimates, the Projected Consumer Price Index may be accessed at: <http://amb.nci.nih.gov/cpi.htm>

4. There is a clear distinction between submitting cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of cost or pricing data is met when all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or by specific identification, to the Contracting Officer or an authorized representative. As later information comes into your possession, it should be submitted promptly to the Contracting Officer in a manner that clearly shows how the information relates to the offeror's price proposal. The requirement for submission of cost or pricing data continues up to the time of agreement on price, or an earlier date agreed upon between the parties if applicable.
 5. By submitting your proposal, you grant the Contracting Officer or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price.
- (5) Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data [FAR Clause 52.215-20 (October 1997)]
- (a) Exceptions from cost or pricing data.
 - (1) In lieu of submitting cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.
 - (i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.
 - (ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include--
 - (A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;

- (B) For market-priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;
- (C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.
- (2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.
- (b) Requirements for cost or pricing data. If the offeror is not granted an exception from the requirement to submit cost or pricing data, the following applies:
 - (1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15-2 of FAR 15.408.
 - (2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision)

Alternate I (October 1997). As prescribed in 15.408(l), substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision:

- (b) (1) The offeror shall submit cost or pricing data and supporting attachments in the following format:

The format specified in paragraph L.2.c.(4) Cost and Pricing Data, subparagraph 3. Formats for Submission of Line Item Summaries shall be used for the submission cost information. Submission of all other cost or pricing data shall be in accordance with Table 15-2 in FAR 15.408.

(6) Total Compensation Plan - Instructions

Specific instructions for the submission of this document are outlined in SECTION L.1.a. of this RFP.

- a) Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors included in the Competitive Range will be required to submit a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.

***** (NOTE: Select the appropriate information contained in the brackets in the above paragraph. When using Just In Time, only those offerors in the competitive range need to submit a plan at that time. Otherwise all offerors need to submit this plan in the original submission.) *****

- b) The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).

- c) Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

(7) Total Compensation Plan - Evaluation

a) **Total Compensation Plan (Professional Employees)**

In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

b) **Cost (Professional Compensation)**

Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

c) **Other (Labor Relations)**

An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

d) **Federal Acquisition Regulation Clauses incorporated by Reference**

FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees (FEBRUARY 1993).

(8) Qualifications of the Offeror

- a) You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

(1) **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities that can be devoted to the project may be appropriate.

(2) **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

(3) **Performance History**

Performance history is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

(4) **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

(5) **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

(9) **Other Administrative Data**

a) **Property**

- (1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:
 - (a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.
 - (b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.
- (2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.
- (3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractors Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

b) **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38 (MAY 1999)**

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

- (1) The solicitation number (or other procurement identification number).
- (2) The offeror's name and remittance address, as stated in the offer.
- (3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
- (4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
- (5) The offeror's account number and the type of account (checking, savings, or lockbox).
- (6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.

- (7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

c) Financial Capacity

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

d) Incremental Funding

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

HHSAR 352.232-75, Incremental Funding (January 2001)

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

- (b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions.

(End of provision)

e) Facilities Capital Cost of Money, FAR 52.215-16, (October 1997)

(This is applicable if you are a commercial organization.)

- (a) Facilities capital cost of money [(see FAR 15.408(h)] will be an allowable cost under the contemplated contract, if the criteria for allowability in subparagraph 31.205-10(a)(2) of the Federal Acquisition Regulation are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.
- (b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

☐ The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

☐ The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

(10) Subcontractors

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

- a) Willingness to perform as a subcontractor for specific duties (list duties).
- b) What priority the work will be given and how it will relate to other work.
- c) The amount of time and facilities available to this project.
- d) Information on their cognizant field audit offices.
- e) How rights to publications and patents are to be handled.
- f) A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

<http://ocm.od.nih.gov/contracts/rfps/FDP/PDPclausecover.htm>

(11) Offeror's Annual Financial Report

All offerors included in the competitive range will be required to submit a copy of the organization's most recent annual financial report.

(12) Representations and Certifications

One copy of the Representations and Certifications attached as Section K shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor.

(13) Travel Costs/Travel Policy

a) **Travel Costs - Commercial**

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b) **Travel Policy**

All offerors included within the competitive range will be required to submit one copy of their written travel policy. A written travel policy for any proposed subcontractors shall also be submitted at that time. If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

SECTION M - EVALUATION FACTORS FOR AWARD
U.S. Based Collaboration In Emerging Viral and Prion Diseases
NIH-NIAID-DMID-02-24

1. GENERAL

The major evaluation factors for this solicitation include technical, cost/price factors, and Small Disadvantaged Business (SDB) Participation. Although technical factors are of paramount consideration in the award of the contract, cost/price and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make awards to the Offerors whose proposals provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

2. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

SDB participation will not be scored, but the Government's conclusions about overall commitment and realism of the offeror's SDB Participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the Offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the Offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform. Offers will be evaluated on the following sub-factors:

- (a) Extent to which SDB concerns are specifically identified
- (b) Extent of commitment to use SDB concerns
- (c) Complexity and variety of the work SDB concerns are to perform
- (d) Realism of the proposal
- (e) Extent of participation of SDB concerns in terms of the value of the total acquisition

3. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

FOR THE UNITS STUDYING CONVENTIONAL EMERGING VIRUSES AND FLAVIVIRUSES

A. SCIENTIFIC CONSIDERATIONS

60 POINTS

Statement of Work Item 1: 30 POINTS

Quality and suitability of the proposal for studies concerning basic virology, pathogenesis and immunology.

- Establish and maintain the ability to rapidly isolate, cultivate, identify and characterize new viral diseases or recognized diseases emerging in new regions.
- Establish and/or maintain animal models and cell culture systems to evaluate: the pathogenic potential of viruses, the immunologic response associated with disease progression and the immunologic basis and immune correlates of natural protective immunity. As designated by the Project Officer, further characterize and/or modify these models or develop other models to improve model utility. The contractor may be required to use animal models other than the one proposed if well-characterized animal models become available.

- Maintain the ability to develop and utilize relevant assays to assess the immunologic status of humans and potentially important animal host species.
- Maintain the ability to assess genetic strain variation and correlate these changes with factors influencing pathogenesis or emergence.
- When designated by the Project Officer, perform pre-clinical, animal model-based evaluation of newly developed vaccines or drug therapies for emerging viruses.
- At the specific request of the Project Officer, provision shall be made to obtain and preserve samples of viruses or animal tissues and fluids. Samples shall be sent, at the direction of the Project Officer, to another contractor or grantee that may perform additional experiments with, or analysis on, the samples. The Contractor shall cooperate or collaborate with other investigators as requested.

Statement of Work Item 2: 30 POINTS

Quality and suitability of the proposal for studies concerning viral epidemiology, and ecological and environmental factors affecting emerging viral infections.

- Establish a program to define the natural association of emerging viruses with their vectors or hosts, and their roles during maintenance and emergence of viruses. Within this program, attempt to determine if the emergence of a disease resulted from the influence of natural, man-made, or climate-induced environmental changes. Where possible an analysis of the predictive value of information from these studies should be performed.
- Establish the capacity and expertise needed to perform epidemiological studies in the field to quickly determine susceptible hosts and vectors that play an important role during emergence of disease.
- Expand and maintain the capacity to perform vector specific studies on: the ecology, biology, and physiology of important vector species and on the identification of bridge vectors that transmit viruses to humans. Analyze the biotic and abiotic elements of an ecosystem of interest to quantify the vector and reservoir species abundance, distribution, population structure, survivorship, food sources, predators, infection status, insecticide resistance status, etc. relative to a particular disease transmission process. Models should include habitat structure parameters and human density / distribution / and exposure parameters. An example of this would be study of the rodent, avian and mosquito species abundant in areas of the US where West Nile virus transmission occurs. Other emerging viral infections are equally valid as topics of study. Develop a database of information generated by these studies for later use by investigators who will develop and validate predictive models of disease transmission to humans.
- Establish and/or maintain the ability to perform molecular epidemiological studies to follow natural genetic strain variation.

B. PERSONNEL and MANAGEMENT

25 POINTS

Statement of Work Item 5: 25 POINTS

Documentation regarding adequacy of the management plan and mix of staff, and organizational structure for the conduct of the project. Documented evidence of the qualifications, experience, time commitment and availability of all technical personnel in relation to their proposed roles, and of the Principal Investigator in managing complex projects of a similar nature.

- Establish and manage laboratory facilities to support the various studies.
- Supervise, coordinate, and perform the tasks outlined in the Work Statement. Formulate a balanced budget to perform the tasks outlined in the work statement.
- At the direction of the Project Officer, re-direct resources to address a potential urgent public health threat. Each center will provide a plan showing its capability to quickly design, review and undertake pilot projects.
- Conduct at least one meeting per year to discuss results and future plans with key investigators and subcontractors within the study consortia. At the Project Officers request, conduct conference telephone calls.
- At the Project Officers need, send representatives to attend and participate in one 2 day meeting per year in Bethesda to discuss results and future plans. The purpose of these meetings will be to share data and allow the transmittal of encouraging approaches to other scientists.

- Conduct work in accordance with the Biosafety in Microbiological and Biomedical Laboratories guidelines, and NIH guidelines for animal care and Human use. All the units should have the capacity to study these agents at Biosafety Level 3.
- Establish electronic message and document transfer capability with the Project Officer. The NIAID is connected to the INTERNET and uses IBM-compatible computers.
- Establish within each unit a training component to help educate pre and postdoctoral investigators.

C. FACILITIES

15 POINTS

Documentation regarding the availability and adequacy of the facilities and equipment to carry out the studies proposed, including BSL 3 labs.

TOTAL:

100 POINTS

FOR THE UNITS STUDYING PRIONS AND VIRUSES-LIKE AGENTS

A. SCIENTIFIC CONSIDERATIONS

60 POINTS

Statement of Work Item 3: 30 POINTS

Quality and suitability of the proposal for studies concerning prion diseases in general and TSE animal diseases with the potential to transmit to humans.

- Establish and maintain the ability to isolate, identify and characterize TSE agents that are new or that have transmitted to a new host.
- Establish and/or maintain animal models and cell culture systems to evaluate the potential for transmission (inter-and intra-species) and pathogenesis of TSE agents. Approaches shall include, but not be limited to evaluating the impact of factors such as PrP strain and host genotype. As designated by the Project Officer, further characterize and/or modify these models or develop other models to improve model utility. The contractor may be required to use animal models other than the one proposed if well-characterized animal models become available.
- Establish and/or maintain the ability to assess TSE agent strain variation and correlate these changes with factors influencing transmissibility, host range, and pathogenesis.
- Where needed, perform pre-clinical, animal model-based evaluation of newly developed prophylaxes or therapies for TSE infection and disease. These will likely involve identification and maintenance of suitable animal models of disease to allow studies of potential prevention/treatment therapies. Depending on the candidate, evaluation will include documentation of: dose/response, overall efficacy at preventing disease, safety, reactogenicity or toxicity, and the effect of the timing of administration relative to exposure.
- At the specific request of the Project Officer, provision shall be made to obtain and preserve samples of infectious material or other animal tissues and fluids. Samples shall be sent, at the direction of the Project Officer, to another contractor or grantee that may perform additional experiments with, or analysis on, the samples. Maintain a capacity to develop, analyze and distribute reagents, infectious material, molecular clones, and transgenic mice that will be needed by qualified investigators to facilitate overall research in TSE infections. The Contractor shall cooperate or collaborate with other investigators as requested.

Statement of Work Item 4: 30 POINTS

Quality and suitability of the proposal for studies implementing a systematic approach to furthering our understanding of the ecologic and environmental factors influencing emergence, spread and distribution of TSEs threatening the U.S.

- Establish research focusing on the natural association of a TSE with its host(s), and their roles during maintenance and emergence of TSEs.
- Evaluate and define the effect on the intra- and inter-species spread of TSEs of: natural, man-made, or climate-induced environmental change; alterations in host population density and distribution; public health practices, altered social/behavioral practices, or modern technological developments. Where possible an analysis of the predictive value of information from these studies should be performed.
- Develop, when needed, the epidemiologic tools to implement surveillance of infection in relevant populations.
- Implement incidence/prevalence surveys in the populations to provide the necessary background information to conduct future prevention and/or therapeutic trials.
- Implement a system to collect and characterize TSE infectious material derived from the unit's research efforts studies.
- Establish the capacity and expertise needed to perform epidemiological studies in the field to quickly determine susceptible hosts that play an important role during emergence of disease.
- Develop a program to help improve surveillance of TSEs. The primary aim will not be surveillance per se, but research within this objective, such as the development of improved diagnostic reagents and assays. Develop where needed, approaches for the more effective diagnosis
- Establish strategic national and international collaborations needed to quickly determine and analyze the issues relevant to the natural emergence of TSEs, and to determine potential targets for preventative and therapeutic agents.

B. PERSONNEL and MANAGEMENT

25 POINTS

Statement of Work Item 5: 25 POINTS

Documentation regarding adequacy of the management plan and mix of staff, and organizational structure for the conduct of the project. Documented evidence of the qualifications, experience, time commitment and availability of all technical personnel in relation to their proposed roles, and of the Principal Investigator in managing complex projects of a similar nature.

- Establish and manage laboratory facilities to support the various studies.
- Supervise, coordinate, and perform the tasks outlined in the Work Statement. Formulate a balanced budget to perform the tasks outlined in the work statement.
- At the direction of the Project Officer and/or the Contracting Officer, rapidly re-direct resources to address a potential urgent public health threat, such as a bioterrorism event. Each unit will provide a plan showing its capability to quickly design, review and undertake such pilot projects.
- Conduct at least one meeting per year to discuss results and future plans with key investigators and subcontractors within the study consortia. At the Project Officers request, conduct conference telephone calls.
- At the Project Officers need, send representatives to attend and participate in one 2 day meeting per year in Bethesda to discuss results and future plans. The purpose of these meetings will be to share data and allow the transmittal of encouraging approaches to other scientists.
- Conduct work in accordance with the Biosafety in Microbiological and Biomedical Laboratories guidelines, and NIH guidelines for animal care and Human use. All the units should have the capacity to study these agents at Biosafety Level 3.
- Establish electronic message and document transfer capability with the Project Officer. The NIAID is connected to the INTERNET and uses IBM-compatible computers.
- Establish within each unit a training component to help educate pre and postdoctoral investigators.

C. FACILITIES

15 POINTS

Documentation regarding the availability and adequacy of the facilities and equipment to carry out the studies proposed, including BSL-3 labs.

TOTAL:

100 POINTS